NDA 20204/S-076

SUPPLEMENT APPROVAL

Bayer HealthCare LLC
Attention: Joanna Fleming
Sr. Associate Director, Regulatory Affairs
100 Bayer Boulevard
Whippany, NJ 07981

Dear Ms. Fleming:

Please refer to your supplemental new drug application (sNDA) dated and received May 1, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Aleve (naproxen sodium) tablet, 220 mg.

This Prior Approval supplemental new drug application provides for graphics design refresh on "Aleve" tablet and "Aleve Back & Muscle Pain" tablet packaging.

APPROVAL & LABELING

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

LABELING

Submit final printed labeling (FPL), as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the enclosed labeling, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Labeling	**Date Submitted**
Regular-shaped tablets	
10-ct vial (immediate container)- Aleve regular-shaped tablets	May 1, 2020
10-ct vial with backer card (outer container)- Aleve regular-shaped tablets	May 1, 2020
10-ct vial with backer card (immediate container)- Aleve regular-shaped tablets	May 1, 2020
24-ct carton (outer container)- Aleve regular-shaped tablets	May 1, 2020
24-ct bottle (immediate container)- Aleve regular-shaped tablets	May 1, 2020
50-ct carton (outer container)- Aleve regular-shaped tablets	May 1, 2020

50-ct bottle (immediate container)- Aleve regular-shaped tablets	May 1, 2020
90-ct carton (outer container)- Aleve regular-shaped tablets	May 1, 2020
90-ct bottle (immediate container)- Aleve regular-shaped tablets	May 1, 2020
200-ct *Easy Open Arthritis cap* (stand-alone bottle)- Aleve regular-shaped tablets	May 1, 2020
320-ct *Soft Grip Arthritis cap* (stand-alone bottle)- Aleve regular shaped tablets	May 1, 2020
Capsule-shaped tablets	
6-ct blister card carton (outer container)- Aleve capsule-shaped tablets	May 1, 2020
24-ct carton (outer container) - Aleve capsule-shaped tablets	May 1, 2020
24-ct bottle (immediate container)- Aleve capsule-shaped tablets	May 1, 2020
50-ct carton (outer container) - Aleve capsule-shaped tablets	May 1, 2020
50-ct bottle (immediate container) - Aleve capsule-shaped tablets	May 1, 2020
90-ct carton (outer container) - Aleve capsule-shaped tablets	May 1, 2020
90-ct carton (outer container) - Aleve capsule-shaped tablets	May 1, 2020
200-ct carton (outer container) - Aleve capsule-shaped tablets	May 1, 2020
200-ct bottle (immediate container) - Aleve capsule-shaped tablets	May 1, 2020
270-ct (stand-alone bottle) - Aleve capsule-shaped tablets	May 1, 2020
24-ct *Soft Grip Arthritis cap* (stand-alone bottle)- Aleve capsule-shaped tablets	May 1, 2020
50-ct *Soft Grip Arthritis cap* carton (outer container) - Aleve capsule-shaped tablets	May 1, 2020
50-ct *Soft Grip Arthritis cap (*stand-alone bottle*)* - Aleve capsule-shaped tablets	May 1, 2020
90-ct *Easy Open Arthritis cap (*stand-alone bottle) - Aleve capsule-shaped tablets	May 1, 2020
270-ct *Soft Grip Arthritis cap* carton (outer container) Aleve capsule-shaped tablets	May 1, 2020
270-ct *Soft Grip Arthritis cap* bottle (immediate container) - Aleve capsule-shaped tablets	May 1, 2020
320-ct (stand-alone bottle) - Aleve capsule-shaped tablets	May 1, 2020
Back & Muscle Pain regular-shaped tablets	
10-ct vial (immediate container)-Aleve Back and Muscle Pain regular-shaped tablets	May 1, 2020
24-ct carton (outer container)-Aleve Back and Muscle Pain regular shaped tablets	May 1, 2020
24-ct bottle (immediate container)-Aleve Back and Muscle Pain regular shaped tablets	May 1, 2020

50-ct carton (outer container)-Aleve Back and Muscle Pain regular shaped tablets	May 1, 2020
50-ct bottle (immediate container)-Aleve Back and Muscle Pain regular shaped tablets	May 1, 2020
90-ct carton (outer container)-Aleve Back and Muscle Pain regular shaped tablets	May 1, 2020
90-ct bottle (immediate container)-Aleve Back and Muscle Pain regular shaped tablets	May 1, 2020
200-ct carton (outer container)-Aleve Back and Muscle Pain regular shaped tablets	May 1, 2020
200-ct bottle (immediate container)-Aleve Back and Muscle Pain regular shaped tablets	May 1, 2020
250 count carton (outer container)- Aleve Back and Muscle Pain tablets	May 1, 2020
250 count bottle (immediate container)- Aleve Back and Muscle Pain tablets	May 1, 2020
Aleve gelatin coated capsule-shaped tablets	
40-ct *Soft Grip Arthritis cap* carton (outer container)-Aleve gelatin coated capsule-shaped tablets	May 1, 2020
40-ct *Soft Grip Arthritis cap* bottle (immediate container)-Aleve gelatin coated capsule-shaped tablets	May 1, 2020
160-ct *Easy Open Arthritis cap* (stand-alone bottle)-Aleve gelatin coated capsule-shaped tablets	May 1, 2020

The FPL should be submitted electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*.[1] For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 20204/S-076**." Approval of this submission by FDA is not required before the labeling is used.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at FDA.gov.[2] Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call LCDR Sally Doan, Regulatory Project Manager, at 301-796-8025.

Sincerely,

{See appended electronic signature page}

Nushin Todd, MD, PhD
Acting Deputy Director
Division of Nonprescription Drugs I
Office of Nonprescription Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Carton and Container Labeling

[1] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

[2] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

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This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

NUSHIN F TODD
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